NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

October 4, 2024

Luke Santillo
Luke.Santillo@davita.com

Exempt from Review

Record #:	**4602**
Date of Request:	October 3, 2024
Facility Name:	Arden Dialysis
FID #:	150248
Business Name:	DaVita, Inc.
Business #:	600
Project Description:	Temporarily add two dialysis stations to the facility for a total of 16 dialysis stations while Hendersonville Dialysis Facility is being repaired
County:	Buncombe

Dear Mr. Santillo:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced proposal is exempt from certificate of need review in accordance with G.S. 131E-184(a)(5). Therefore, you may proceed to **temporaril**y offer, develop or establish the above referenced project without a certificate of need.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Agency. Changes in a project include but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; (5) any increase in the number of square feet to be constructed; and (6) permanent relocation of dialysis stations.

If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Ena Lightbourne, Project Analyst

Micheala Mitchell, Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

October 1, 2024

Ms. Azzie Conley, Chief
Acute and Home Care Licensure and Certification Section
Division of Health Service Regulation
North Carolina Department of Human Resources
1205 Umstead Drive
Raleigh, NC 27603

RE: Temporary Increase in Dialysis Stations in response to Hurricane Helene

Dear Ms. Conley:

Hurricane Helene caused extensive damage to the Hendersonville Dialysis Center, Provider Number 34-2564. We anticipate the repairs for this clinic will take months. In the interim, we are transporting the majority of the center's 78 patients to Forest City to treat at our Dialysis Care of Rutherford County center, a trip of approximately 40 miles one way. To reduce the travel burden on our patients, DaVita is submitting a request to increase the dialysis station capacity at Arden Dialysis and provide the following information:

1. Attached is a CMS Form 3427 for Arden Dialysis.

2. This request for a temporary increase in dialysis station capacity is for the number of additional stations detailed below:

Facility	FID Number	Provider Number	County	Currently Certified	Additional Number of Stations Requested	Total
Arden Dialysis	150248	34-2756	Buncombe	14	2	16

3. The space that will be utilized in these existing facilities has plumbing and electrical wiring through the walls to accommodate the additional stations. A floor plan is attached. We anticipate utilizing these additional stations until the Hendersonville Dialysis Center is operational, beginning on a proposed effective date of October 4, 2024.

4. As Vice President for DaVita's operations in Western North Carolina, I certify that:
   a. This request is necessary for the public health and safety in the geographic area served;
   b. The physical facilities to be used are adequate to safeguard the health and safety of the dialysis patients served; and
   c. The dialysis patients served will receive appropriate care and their health and safety will be safeguarded.

Sincerely,

Tammy Leahy
Division Vice President
DaVita Kidney Care

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0360

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-0360**. The time required to complete this information collection is estimated to average of **20 minutes** per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

END STAGE RENAL DISEASE APPLICATION AND SURVEY AND CERTIFICATION REPORT

PART I – APPLICATION – TO BE COMPLETED BY FACILITY

1. Type of Application/Notification (check all that apply; if "Other," specify in "Remarks" section [Item 33]): (V1)

☐ 1. Initial ☐ 2. Recertification ☐ 3. Relocation ■ 4. Expansion/change of services ☐ 5. Change of ownership

■ 6. Other, specify Hurrican Helene Response Increase station count by 2

2. Name of Dialysis Facility: ARDEN DIALYSIS		3. CCN: 34-2756
4. Street Address: 2621 Hendersonville Rd		5. NPI: 1497398416
6. City: Arden	7. County: Buncombe	8. Fiscal Year End Date: 12/31
9. State: NC	10. Zip Code: 28704-9226	11. Administrator's Email Address: Tammy.Lance@davita.com
12. Telephone No.: (828) 630-1038	13. Facsimile No.: (828) 630-1055	14. Medicare Enrollment (CMS 855A) completed? ■ Yes ☐ No ☐ NA

15. Dialysis Facility Administrator Name: Tammy Lance
Business Address: 2621 Hendersonville Rd
City: Arden State: NC Zip Code: 28704-9226 Telephone No: (828) 630-1038

16. Ownership (V2) ■ 1. For Profit ☐ 2. Not for Profit ☐ 3. Public

17. Is this dialysis facility independent (i.e., not owned or managed by a hospital)? (V3) ■ 1. Yes ☐ 2. No
Is this dialysis facility owned and managed by a hospital and on the hospital campus (i.e., hospital-based)? (V4) ☐ 1. Yes ■ 2. No
Is this dialysis facility owned and managed by a hospital and located off the hospital campus (i.e., satellite)? (V5) ☐ 1. Yes ■ 2. No

18. Is this dialysis facility located in a SNF/NF (LTC) (check one): (V6) ☐ 1. Yes ■ 2. No
If SNF/NF owned and managed by a hospital: hospital name: (V7)_____ CCN: (V8)_____
If Yes, SNF/NF name: (V9)_____ CCN: (V10)_____

19. Is this dialysis facility owned &/or managed by a multi-facility organization? (V11) ☐ 1. No ■ 2. Yes, Owned ☐ 3. Yes, Managed
If Yes, name of multi-facility organization: (V12) DaVita Inc.
Multi-facility organization's address: 2000 16th St, Denver, CO 80202

20. Current modalities/services for dialysis facilities requesting recertification only (check all that apply): (V13)

■ 1. In-center Hemodialysis (HD) ☐ 2. In-center Peritoneal Dialysis (PD) ☐ 3. In-center Nocturnal HD
☐ 4. Home HD Training & Support ☐ 5. HD in LTC
☐ 6. Home PD Training & Support ☐ 7. PD in LTC ☐ 8. Dialyzer Reuse

21. New modalities/services being requested (check all that apply; must have 1 permanent patient for any modality requested): (V14)

☐ 1. In-center HD ☐ 2. In-center PD ☐ 3. In-center Nocturnal HD
☐ 4. Home HD Training & Support ☐ 5. HD in LTC
☐ 6. Home PD Training & Support ☐ 7. PD in LTC ☐ 8. Dialyzer Reuse ■ 9. N/A

NOTE: For dialysis in more than 1 LTC facility, record this same information in the "Remarks" (item 33) section or attach list

22. Does the dialysis facility have any dialysis (PD/HD) patients physically receiving dialysis within long-term care (LTC) facilities? (V15)
☐ 1. Yes ■ 2. No LTC (SNF/NF) facility name: (V16)_____ CCN: (V17)_____
Staffing for home dialysis in LTC provided by: (V18) ☐ 1. This dialysis facility ☐ 2. LTC staff ☐ 3. Other, specify:_____
Number of dialysis residents by modality receiving dialysis within this LTC facility: (V19) ☐ 1. HD_____ ☐ 2. PD_____

23. Number of dialysis patients currently on census:

END STAGE RENAL DISEASE APPLICATION AND SURVEY AND CERTIFICATION REPORT

In-Center HD: (V20) 49 In-Center Nocturnal HD: (V21) ____ In-Center PD: (V22) ____

Home PD: (V23) ____ Home HD <= 3x/week: (V24) ____ Home HD >3x/week: (V25) ____

24. Number of **currently** approved in-center dialysis stations: (V26) 14 Are onsite home training room(s) provided? (V27) ☐ 1. Yes ■ 2. N/A

25. Additional in-center stations requested: (V28) 2 or ☐ None

26. How is isolation provided? (V29) ■ 1. Room ☐ 2. Area (existing 2/9/2009 only) ☐ 3. CMS Waiver/Agreement (Attach copy)

27. If applicable, number of hemodialysis stations designated for isolation: (V30) 1

28. Days/times for in-center shifts or operating hours if home only (check all days that apply and complete time field in military time): (V31)

1st in-center shift starts or home only facility opens: M 05:45 T 05:45 W 05:45 Th 05:45 F 05:45 Sat 05:45 Sun ____

Last in-center shift ends or home only facility closes: M 17:00 T 17:00 W 17:00 Th 17:00 F 17:00 Sat 17:00 Sun ____

29. Dialyzer reprocessing: (V32) ☐1. Onsite ☐ 2. Centralized/Offsite ■ 3. N/A

30. Staff (List full-time equivalents): Registered Nurse: (V33) 2 Certified Patient Care Technician: (V34) 4

LPN/LVN: (V35) 1 Technical Staff (water, machine): (V36) 1

Registered Dietitian: (V37) 1 Masters Social Worker: (V38) 1

Others: (V39) ____

31. State license number (if applicable): (V40) NA	32. Certificate of Need required? (V41) ☐ 1. Yes ☐ 2. No ■ 3. NA Hurricane Helene Response

33. Remarks (copy if more and attach additional pages if needed):

In response to Hurricane Helene, increase station count by 2
We will be temporarily expanding our in-center station count from 14 to 16
14 + 2 = 16

34. The information contained in this Application Survey and Certification Report (Part I) is true and correct to the best of my knowledge. I understand that incorrect or erroneous statements may cause the request for approval to be denied, or facility approval to be rescinded, under 42 C.F.R. 494.1 and 488.604 respectively.

I have reviewed this form and it is accurate:

Signature of Administrator/Medical Director	Title	Date
	Director, Health Care Planning	10/1/24

PART II TO BE COMPLETED BY STATE AGENCY

35. Medicare Enrollment (CMS 855A recommended for approval by the Medicare Administrative Contractor)? (V42) ☐ 1. Yes ☐ 2. No

(Note: approved CMS 855A required prior to certification)

36. Type of Survey: (V43) ☐ 1. Initial ☐ 2. Recertification ☐ 3. Relocation ☐ 4. Expansion/change of services ☐ 5. Change of ownership ☐ 6. Complaint ☐ 7. Revisit ☐ 8. Other, specify ____

37. State Region: (V44) ____	38. State County Code: (V45) ____

39. Network Number: (V46) ____

My signature below indicates that I have reviewed this form and it is complete.

40. Surveyor Team Leader (sign)	41. Name/Number (print)	42. Professional Discipline *(Print)*	43. Survey Exit Date
			:

INSTRUCTIONS FOR FORM CMS-3427

PART I – DOCUMENTATION NEEDED TO PROCESS FACILITY APPLICATION/NOTIFICATION TO BE COMPLETED BY APPLICANT

A completed request for approval as a supplier of End Stage Renal Disease (ESRD) services in the Medicare program (Part I – Form CMS-3427) must include a copy of the Certificate of Need approval, if such approval is required by the state.

TYPE OF APPLICATION (ITEM 1)

Check appropriate category. A "change of service" refers to an addition or deletion of services, e.g. home dialysis, dialysis in LTC, dialyzer reuse, in-center nocturnal HD, in-center PD, etc. "Expansion" refers to addition of in-center stations. If you relocate one of your services to a different physical location, you may be required to obtain a separate CCN for that service at the new location.

IDENTIFYING INFORMATION (ITEMS 2-19)

Enter the name and address *(actual physical location)* of the dialysis facility where the services are performed. If the mailing address is different, show the mailing address in Remarks (*Item 33*). Check the applicable blocks (*Item 17* and *Item 18*) to indicate the dialysis facility's hospital and/or SNF/NF affiliation, if any. If so, enter the CCN of the hospital and/or SNF/NF. Check whether the dialysis facility is owned and/or managed by a "multi-facility" organization (*Item 19*) and provide the name and address of the parent organization. A "multi-facility organization" is defined as a corporation or a LLC that owns more than one dialysis facility.

TYPES OF MODALITIES/SERVICES, DIALYSIS STATIONS, AND DAYS/HOURSOF OPERATION (ITEMS 20-29)

Check the modalities/services that are already offered ("current modalities/services") by a dialysis facility requesting recertification (*Item 20*). Check N/A or check each **NEW** modality/service for which you are requesting approval. Any new modality/service must be requested on the CMS-3427 and filed with the State agency. At the time of survey, one permanent patient must be on the dialysis facility's census in-center or in training/trained by the facility for each modality requested (*Item 21*). Note that dialysis facilities providing home therapies must provide both training and support. If you are requesting to offer home training and support **only** (*Item 21*), you must have a functional plan/arrangement to provide backup dialysis as needed. If you request any home training and support program (*Item 21*), you must also indicate "Yes" for a training room (only count stations for in-center dialysis, not for home training) (*Item 24*). **If you currently provide or support dialysis within one or more LTC facilities (SNF/NF), complete *Item 22* and list for all LTCs: name, CCN, staffing provided by, and number of dialysis patients treated by modality under Remarks (*Item 33*). New requests for dialysis within any LTC facility require completion of *Item 22* (and 33 if applicable) and submission of this form to the State agency prior to survey.** You must answer *Yes* (*Item 22*) and have at least one LTC dialysis resident for addition of services for dialysis in LTC. Enter the number of additional in-center stations for which you are asking approval (*Item 25*). Provide information on isolation *(Items 26-27)*. Dialysis facilities not existing prior to October 14, 2008 which do not have an isolation room must attach evidence of CMS waiver and written agreement with geographically proximal facility with isolation room. Provide current information on all days and start time for the first shift and end time for the last shift of in-center patients (in military time) for each day of operation. If the dialysis facility offers home training and support only, provide current operating hours for each day *(Item 28)*. Provide information on dialyzer reprocessing *(Item 29)*.

STAFFING (ITEM 30)

"Other" includes non-certified patient care technicians, administrative personnel, etc. To calculate the number of full-time equivalents of any discipline (*Item 30*), add the total number of hours that all members of that discipline work at this dialysis facility and enter that number in the numerator. Enter into the denominator the number of hours that facility policy defines as full-time work for that discipline. Report FTEs in 0.25 increments only. Example: An RD works 20 hours a week at Facility A. Facility A defines full time work as 40 hours/week. To calculate FTEs for the RD, divide 20 by 40. The RD works 0.50 FTE at Facility A.

LICENSING AND CERTIFICATE OF NEED, IF APPLICABLE (Items 31-32)

If your state requires licensing for ESRD facilities, include your current license number in Item 31. If your state requires a Certificate of Need (CON) for an initial ESRD or for the change you are requesting, mark the applicable box in Item 32 and include a copy of the documentation of the CON approval.

REMARKS (ITEM 33)

You may use this block for explanatory statements related to Items 1-32.

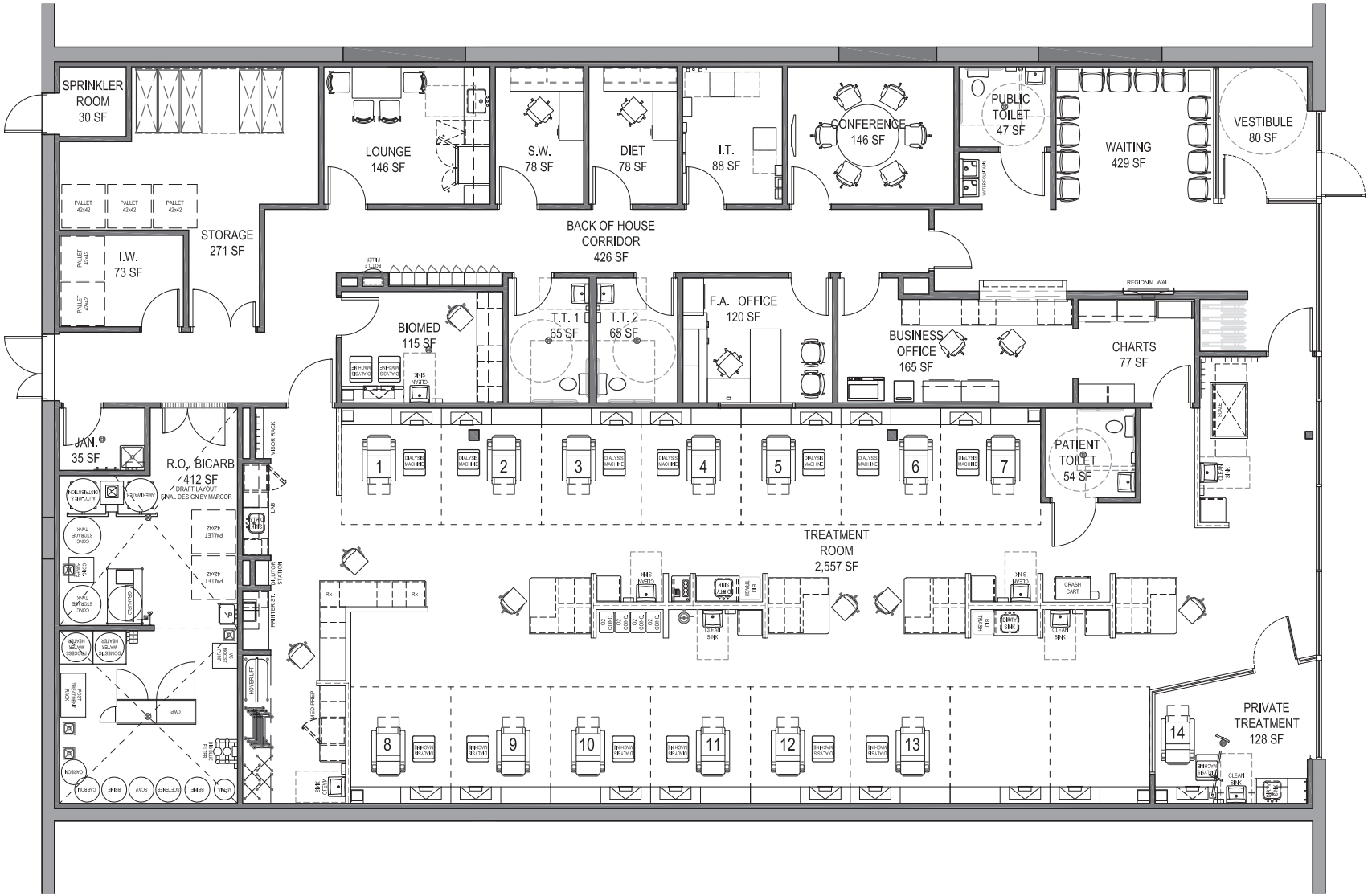
The administrator/medical director signs and dates. Upon completion, forward a copy of form CMS-3427 (Part I) to the State agency.

PART II - TO BE COMPLETED BY STATE AGENCY

The surveyor should review and verify the information in Part I with administrator or medical director and complete Part II of this form.

Recognize that CMS cannot issue a CCN for an initial survey until all required steps are complete, including recommended approval of the CMS-855A by the applicable MAC. Complete the Statement of Deficiencies (CMS Form 2567) in ASPEN. Complete the CMS-1539 in ASPEN entering recommended action(s). All required information must be entered in ASPEN and uploaded in order for the survey to be counted in the state workload.

Ex K-5



KC STUDIO ARCHITECTURE CREATING · CONNECTING · COLLABORATING	5 W Hargett Street Suite 1012 Raleigh, NC 27601 919 702 3702	**PROJECT:** Arden Dialysis 14 Stations in 6,260 SF	**SHEET TITLE:** CON Application	**PROJECT NUMBER:** 004 SCALE: 1/8" = 1'-0" DRAWN BY: EP	**ISSUE DATE:** 11/06/2019	CON

From: Mitchell, Micheala L
To: Stancil, Tiffany C
Subject: FW: [External] Request for temporary dialysis station expansion in response to Hurricane Helene
Date: Wednesday, October 2, 2024 3:45:03 PM
Attachments: image001.png
DaVita Hurrican Helene Response Request to Add Stations - Arden Dialysis.pdf
CMS-3427_Arden Hurricane Response Station Increase (14 to 16).pdf
Arden Floor Plan.pdf

Hey!

I saw some emails flying around about you, but it's been such a crazy day that this is the first opportunity that I've had to email you. I hope that you are feeling better and getting some rest Tiffany.

This request came in to me and Ena this morning. Would you mind logging it as an exemption? Ena is aware of it, but I'd just follow whatever procedure you normally follow when assigning.

Thank you and let me know if you need anything okay? I mean that.

Micheala

Micheala Mitchell, JD
NC Department of Health and Human Services
Division of Health Service Regulation
Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704
Office: 919 855 3879
Micheala.Mitchell@dhhs.nc.gov

From: Luke Santillo <Luke.Santillo@davita.com>
Sent: Tuesday, October 1, 2024 6:32 PM
To: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>
Cc: Pittman, Lisa <lisa.pittman@dhhs.nc.gov>; Lightbourne, Ena <ena.lightbourne@dhhs.nc.gov>; Esther Fleming <Esther.Fleming@davita.com>
Subject: [External] Request for temporary dialysis station expansion in response to Hurricane Helene

Hi Micheala,
Please find attached a request to temporarily expand Arden Dialysis by two stations. Our

Hendersonville Dialysis Center was flooded this weekend from Hurricane Helene and will take months to repair. We currently have a plan to dialyze the center's 78 patients, but the temporary expansion at Arden Dialysis will allow us to dialyze many of these patients closer to home. We appreciate your quick attention to this matter.

Thanks,
Luke

Luke Santillo
Director, Healthcare Planning
Cell: 980-322-7582 | Fax: 833-214-6977